

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

Device Description:

The Blazer II XP™ Cardiac Ablation Catheter is a quadripolar ring electrode cardiac ablation catheter. It is designed to allow for therapeutic ablation, intracardiac diagnostic recordings, and pacing capabilities. The catheter is available with an 8F-diameter tip and 2 electrode tip lengths, 8mm and 10mm. The 8mm tip is available in both a straight and contour shape, while the 10mm tip is only available in a straight shape. The choice of electrode tip configurations (straight or contour) is left to the discretion of the physician. (Figure 1 illustrates the Blazer II XP™ Catheter with available instrument cable.)

The Blazer II XP™ Catheter is capable of accessing high power (100 Watts/2 Amps) from the EPT-1000 XP Cardiac Ablation Controller (henceforth, referred to as the Controller). The catheter connects to the Controller via the High Power Automatic Personality Module (XP APM). The XP APM provides for additional connection to standard hospital electrophysiology recorders/monitors. Boston Scientific Corporation/EP Technologies recommends operating the Controller in Temperature Control mode to access high power (100 Watts/2 Amps).

• **Note:** The Blazer II XP™ catheter can only access high power (100 Watts/2 Amps) when used with the EPT-1000 XP Cardiac Ablation Controller and the XP APM. Attempting to use the Blazer II XP™ with an APM other than the XP APM results in a maximum delivery of 50 Watts/1 Amp.

For all ablation catheters, radiofrequency (RF) power is delivered between the catheter's distal electrode and commercially available external Dispersive Indifferent Patch (DIP) Electrodes. Dispersive Indifferent Patch Electrodes (Valley Lab Model E7506) were tested with the EPT-1000 XP Cardiac Ablation System to meet safety requirements per ANSI/AAMI Standard 18.

A summary of the technical specifications for the Blazer II XP™ Cardiac Ablation Catheters is provided in Table 3, Technical Specifications.

Indication for Use

The Boston Scientific Corporation Blazer II XP™ Cardiac Ablation Catheter is indicated for use with the EPT-1000 XP Cardiac Ablation Controller and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older.

The EPT-1000 XP™ Cardiac Ablation Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.

Contraindications

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma; and
- via the retrograde approach in patients with aortic valve replacement.

Warnings

Before operating the device, read these warnings carefully:

- Peri-procedural anticoagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic anti-coagulation therapy pre- during and postablation to reduce the incidence of major complications.
- Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:
 - a) Retain temporary external sources of pacing available during ablation.

- b) Reprogram the pacing system temporarily to minimum output or 000 mode to minimize risk of inappropriate pacing.
- c) Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.
- d) Perform complete pacing system analysis on all patients after ablation.
 - Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.
 - Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue.
 - In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
 - If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of thrombus in the left atrial appendage.
 - Do not pass the catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve.

P r e c a u t i o n s

Observe these precautions, before using the device:

- Do not attempt to operate the Controller before thoroughly reading the *E P T-1000 XP Cardiac Ablation Controller & Accessories Operator's Manual*.
- The Blazer II XP™ Cardiac Ablation Catheters are intended for use with the Controller and accessories only.
- Contents are supplied **STERILE** using an ethylene oxide process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious diseases(s) from one patient to another. Contamination of the device may lead to injury, illness or death to the patient.
- The Blazer II XP™ Catheter is highly torqueable. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. *Do not rotate the handle and catheter shaft more than one and one-half times the full rotation (540 degrees).* If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall before resuming rotation of the handle and catheter shaft.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance.
- *Do not use excessive force to advance or withdraw the catheter when resistance is encountered.*
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of RF Powered Catheter Ablation in a fully-equipped electrophysiology laboratory.
- Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize

coagulum, it is recommended that the Catheter periodically be removed and the distal tip cleaned after each line of block.

- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications.
- When using XP Catheters, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of ANSI/AAMI Standard HF-18 be used as the ablation return electrodes or skin burns may result. Use of only one DIP electrode will not allow the operator to fully access the higher power capabilities of the Controller.
- Placement of the DIP electrodes on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.
- During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrodes or failure of an electrical lead.
- ***Do not increase power before checking for obvious defects or misapplication.***
- Regularly inspect and test re-usable cables and accessories.

Potential Adverse Events

Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to:

- air embolism
- allergic reaction (including anaphylaxis)
- anemia
- angina
- arrhythmias, including exacerbation of pre-existing atrial fibrillation
- arterial or pulmonary embolism
- arterial / venous thrombosis
- arterial-venous fistula
- atrioventricular node damage (transient/permanent)
- atypical flutter
- back pain and / or groin pain
- cardiac perforation
- cardiac or respiratory arrest
- cardiac thromboembolism
- catheter entrapment
- cerebral vascular accident
- chest pain / discomfort
- complete heart block
- complications of sedative agents (e.g. aspiration pneumonia)
- congestive heart failure
- death
- effusion (pericardial / pleural)
- endocarditis
- hematoma / bruising
- hemoptysis
- hemorrhage
- hemothorax
- hypotension
- increased phosphokinase level
- infection
- laceration
- myocardial infarction
- nerve palsy or weakness
- pericarditis
- phrenic nerve damage/diaphragmatic paralysis
- pleural effusion
- pleurisy
- pneumothorax

- pulmonary edema
- pseudoaneurysm
- radiation exposure
- seizure
- sinoatrial node damage
- skin burn (defibrillator / cardioverter / radiation)
- tamponade
- temporary complete heart block
- thrombi
- thromboembolism
- transient ischemic attack (TIA)
- valvular damage/insufficiency
- vascular bleeding
- vasovagal reactions
- visual blurring
- worsening chronic obstructive pulmonary disease

Inspection Prior to Use

Prior to use of the EPT-1000 XP™ Cardiac Ablation System, the individual components including the Blazer II XP™ catheter, the EPT-1000 XP Cardiac Ablation Controller, Quick Connect Instrument Cable, XP Automatic Personality Module and Footswitch should be carefully examined for damage or defects as should all equipment used in the procedure.

Do not use defective equipment.

Equipment Required

Intracardiac electrophysiology and cardiac ablation procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. Ancillary materials required to perform cardiac ablation are as follows:

- One (1) - 8 French (8F) hemostatic percutaneous catheter introducer and/or a long introducer sheath to match the 8F diameter of the electrode tip.
- Two (2) - DIP Electrodes meeting ANSI standard HF-18 requirements for electro-surgical electrodes.

Setting up the System

Refer to the *EPT-1000 XP™ Cardiac Ablation Controller & Accessories Operator's Manual* for detailed instructions for connecting the system and setting ablation parameters.

Attaching the DIP Electrodes

Read the manufacturer's manual before installing the DIP Electrode pads

1. Place two DIP electrodes on the patient on a well-vascularized, convex skin surface that is in close proximity to the ablation site (left upper quadrant of the back is suggested unless the patient's scapula is especially prominent or patient is extremely thin). Other possible locations are the upper arm or left flank area.
2. Avoid scar tissue, bony prominence, adipose tissue or distal areas from the heart (thigh), or any areas where fluid may pool. Shave, clean, and dry the application site as needed. Check for wrinkles or folds when applying the pad as these decrease conductivity.
3. Install the two DIP Electrodes connectors into the INDIFFERENT ELECTRODE receptacles located on the XP APM front panel. Figure 2 illustrates the cable configuration for the Blazer II XP™ Catheter, EPT-1000 XP Cardiac Ablation Controller, and XP APM.

Directions for Use

Prior to insertion of the Blazer II XP™ Cardiac Ablation Catheter, prepare the entry site according to standard aseptic practices.

1. Insert the catheter percutaneously into the appropriate vein by the Seldinger technique, using a 8F hemostatic introducer sheath and/or a long sheath.

2. Once inside the vessel, the catheter tip can be deflected as necessary to facilitate advancement into the selected heart chamber.
3. Connect the XP APM to the ISOLATED PATIENT CONNECTOR located on the Controller's front panel using the attached patient cable. Be sure to carefully follow the instructions in the Operator's Manual to connect the XP APM.
4. Connect the Catheter to the model 613 or 651 instrument cables and plug the cables into the XP APM.
5. When the ablation site has been accessed and the tip of the catheter is in contact against the endocardial surface, intracardiac electrogram signals may be obtained. Bipolar electrogram recordings can be recorded between the distal tip electrode and any ring electrode, or between any two ring electrodes even during RF ablation.
6. The Blazer II XP™ or a multi-polar catheter can be used to assess bi-directional conduction across the isthmus.
7. Use lower power first- When first delivering RF energy, begin by using a low power setting (i.e., 50W). If the created lesion is unsuccessful or inadequate, incrementally increase the power output with successive ablation attempts to minimize the potential for thrombus formation and/ or inadvertent damage to cardiac tissues.
8. When the targeted site has been located, the same catheter can be used therapeutically in the "Ablate" mode to deliver RF energy. RF power is delivered to the tissue via the distal tip (ablation) electrode which results in thermal necrosis (ablation) of the arrhythmogenic tissue.
9. Ensure that the ablation parameters are set as instructed in the *EPT-1000 XP™ Cardiac Ablation Controller and Accessories Operator's Manual*.
 - **Note** The Controller automatically adjusts power (up to a maximum of 100 watts), within a user-selected upper power limit, to achieve the desired temperature, in the Temperature Control mode.
10. The catheter tip curve can be straightened completely and deflected in the opposite direction against cardiac tissue, facilitating stability during ablation.
 - **Note** The EPT-1000 XP™ Cardiac Ablation System is designed so that the temperature set limit cannot exceed 80°C in Temperature Control Mode.
11. To begin RF power delivery, press the RF POWER CONTROL Button on the Controller's front panel once or hold the Footswitch down. The POWER Display shows the RF power delivered to the catheter (in watts).
12. During RF delivery, monitor key parameters and adjust therapy delivery accordingly.
13. If any of the following conditions occur during operation, discontinue RF power delivery and perform corrective action as indicated.

If a problem is encountered during the procedure, first ensure that all connections are secure and correct, then follow the steps in Table 1.

Catheter Removal

1. Prior to removing the Catheter, straighten the distal end of the catheter completely.
2. Withdraw the catheter from the vessel.
3. Remove the introducer and/or long introducer sheath and then follow standard practice for management of the insertion site.

Table 1: Correcting Abnormal Conditions

Problems(s)	Possible Cause	Corrective Action Procedure
Lack of	Inadequate contact	1. Discontinue RF delivery.

Temperature Rise	between electrode and tissue.	2. Adjust Catheter position to gain contact and stability. 3. Reinitiate RF delivery.
Low Temperature Fluctuating Temperature Fluctuating Power	Electrode not stable on endocardium.	1. Discontinue RF delivery. 2. Adjust Catheter position to gain contact and stability. 3. Reinitiate RF delivery.
Sudden Drop in Temperature Sudden Rise in Power	Loss of contact or shift in electrode position.	1. Discontinue RF delivery immediately to prevent ablation of nontargeted tissue. 2. Tip position should be assessed using fluoroscopic and electrogram information 3. Reinitiate RF delivery.

SUMMARY OF CLINICAL STUDY

1. Objective

The objective of the study was to evaluate the safety and efficacy of the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories for radiofrequency ablation of sustained or recurrent type I atrial flutter.

2. Study Design

The study was a prospective, multi-center, single-arm study using objective performance criteria and historical control data from the medical literature. Clinical efficacy and safety assessments were performed at one, three and six months and at one and two years following the index procedure.

3. Study Endpoints

The primary endpoints for the study were as follows:

- Acute Procedural Success – defined as the demonstration of bi-directional isthmus block with non-inducible type I atrial flutter with only the use of the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories as assessed at the end of the ablation procedure.
- Six-month Success – defined as demonstration of Acute Success and continued absence of targeted type I atrial flutter for the first six months after the index procedure.
- Complication Rate – refers to major complications experienced by patients exposed to the investigational device which occur within seven days post-procedure.
- Objective Performance Criteria (OPC):
Objective performance criteria (OPC) were prospectively established for all atrial flutter studies by FDA, based on prior experience with supraventricular tachycardia (SVT) ablation studies and consideration by the FDA Circulatory System Devices Panel. The OPC are defined below:

Objective Performance Criteria for Atrial Flutter Ablation

• Endpoint	• OPC	
	• %	• One-sided 95% Confidence Bound ¹
• Acute Success	• 86%	• 80%
• Major Complications	• 3%	• 7%
• Six-Month Success	• 86%	• 80%

¹Exact binomial using a commercially-available software package.

4. Patient Accountability

The table below documents the accountability of patients throughout the study.

Patient Accountability

Patients enrolled in the study	250
Patients not ablated	0
Patients ablated with EPT-1000 XP™ Cardiac Ablation System	250
Patients ablated only with EPT-1000 XP™ Cardiac Ablation System	243
Patients ablated with EPT-1000 XP™ Cardiac Ablation System and non-investigational catheter*	5
Patients ablated only with non-investigational catheter	2

- * Patients were first ablated with the EPT-1000 XP™ Cardiac Ablation System only. If flutter procedure could not be completed, then physicians used another catheter to complete the procedure. These patients were considered acute failures.

5. Patient Demographics

The majority of patients in the study are male (83%, N = 205/243). The average age of the male patients is 60.5 ± 11.1 years. There are 42 (17%) females enrolled in the study, with an average age of 63.4 ± 12.4 years.

6. Results

6a. Intraprocedural Data

The table below describes the intraprocedural data:

Intraprocedural Data (N = 209*)

Description (N)	Mean ± SD	Range
Total # of RF Applications / procedure (N = 209 procedures)	11.5 ± 10.6	1.0 - 86.0
Total Duration of RF Applications (minutes) (N = 209 procedures)	14.6 ± 12.1	2.0 - 74.9
Duration per delivery (seconds) (N = 2405 RF applications)	75.9 ± 37.4	11.0 - 120.0
Maximum Set Power (Watts) (N = 2405 RF applications)	76.9 ± 17.1	30.0 - 100.0
Average delivered power (Watts) (N = 2405 RF applications)	54.3 ± 20.5	6.4 - 96.7
Maximum Set Temperature (°Celsius) (N = 2405 RF applications)	64.2 ± 4.8	45.0 - 80.0
Average delivered temperature (°Celsius) (N = 2405 RF applications)	54.6 ± 6.3	40.5 - 77.9

* Based on RF diskette data received

- RF Application with time set < 6 seconds, temperature set < 6 degrees or duration < 11 seconds are excluded from the analysis
- Maximum power allowed is 100 watts, Maximum temperature allowed is 80° C

The index procedure and fluoroscopy times are shown in the table below.

Fluoroscopy/Procedure Index Times (N = 234)

Description	Number of Procedures	Mean (±SD) Duration	Range
Total Procedure (hours)	234	2.1 (±1.3)	0.3 - 9.8
Ablation Time (hours)	231	0.7 (±0.7)	0.03 - 4.5
Total Fluoroscopy (minutes)	232	28.5 (±20.2)	2.8 - 129.0
Ablation Only Fluoroscopy (minutes)	222	14.8 (±13.8)	0.6 - 102.0

6b. Acute Procedural Success (bi-directional isthmus block)

Acute success evaluation was based on 250 patients treated with the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories. The table below describes the information:

Acute Ablation Outcomes (N=250)

	# Success / # Patients Ablated	Percentage (one-sided 95% confidence bound) ¹
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Acute Success	235/250	94% (91.5%)
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Exact binomial using a commercially-available software package.

6c. Freedom from Atrial Flutter Recurrence at Six-Month Follow-Up

Freedom from atrial flutter recurrence was evaluated in patients in whom bi-directional isthmus conduction block (BDB) and non-inducibility of atrial flutter (AFL) post ablation was achieved and were considered evaluable for an assessment of long-term (6-month) success.

The patients were divided into evaluable at 6 months and not evaluable at 6 months. There were also 30 patients of the total 250 patients that had not completed the 6 month follow-up.

Reasons that patients were classified "not evaluable"

- Treatment with anti-arrhythmic therapy = 31 patients
 - This was defined as treatment with Class IA, IC or III at both the one-month and three-month, or at the 6 month follow-up. The rationale was that this treatment might suppress the recurrence of atrial flutter and obscure the actual rate of recurrence.
- Implanted defibrillators/pacemakers = 11 patients
 - The rationale for not evaluating these patients was that the effect of pacing on atrial flutter is unknown and the presence of pacing might make the assessment of atrial flutter difficult.
- Persistent atrial fibrillation = 1 patient
 - Persistent atrial fibrillation might essentially "overdrive" the atrial flutter. This one patient developed atrial fibrillation shortly after the procedure and remained in that rhythm for the duration of the study.
- Withdrawn consent/lost to follow-up = 6 patients
 - These patients were determined to be not evaluable if they were lost to the study prior to 6 month follow-up.
- Death = 5 patients prior to the 6 month follow-up
 - These patients would have been evaluable if they had a recurrence of atrial flutter and were not on medications that would alter the assessment of that recurrence.

Based on these criteria, information was available on a total of 151 patients. Results are described in the table below.

Freedom from Atrial Flutter at 6 months	
Description	N
Patients ablated only with EPT-1000 XP™ System and successful BDB and AFL non-inducibility (Acute Success)	151
Number of patients free from recurrence	145
Number of patients with recurrence of atrial flutter	6

6d. Adverse Events and Deaths

An adverse event was determined to be any undesirable experience occurring to a subject during the course of the study, whether or not it is related to the device or procedure. A major adverse event was defined as any clinical event which occurred within the first week following the use of the investigational device and was life-threatening; or resulted in permanent impairment of a body function or permanent damage to a body structure; necessitated significant intervention, such as major surgery, to prevent permanent impairment of a body function or permanent damage to a body structure; or required hospitalization or an extended hospital stay.

Twenty-two (22) major adverse events were reported for twenty (20) patients. These events included lower extremity ischemia, cerebral infarct, thrombus (2 events), fractured femur, cerebral emboli, pulmonary embolism, hematoma, pseudoaneurysm (2 events) and AV fistula. Eight patients died during the study. Of the eight deaths, five occurred during the six-month study follow-up period, and all were related to underlying pre-existing conditions.

Major Adverse Events

Of the 250 patients treated with the Blazer II XP™ Cardiac Ablation Catheter and EPT-1000 XP™ Cardiac Ablation Controller and Accessories, twenty-two (22) major adverse events were reported in twenty (20) patients. The major adverse event rate (number of patients with the major adverse events per the number of patients in the study) was 8 % (20 /250).

A detailed review of each adverse event was completed. Several patients had adverse events related to pre-existing non-cardiac disease. Several patients had adverse events related to having an invasive procedure but not relating

specifically to the investigational device or ablation procedure. The table below details the major adverse events (AE) information.

	Days post ablation	Adverse event
1		Atrial tachycardia
2	1	Pacer implant one day post ablation procedure for junctional rhythm *
3	2	Atrial fib
4	0	Laryngotracheitis due to traumatic intubation
5	0	Left buttock induration, treated with narcotics
6	3	Groin hematoma
7	0	Pulmonary embolus *
	3	Fractured femur
8	1	Systemic embolus to legs bilaterally, right popliteal and left tibioperoneal
9	1	Pacemaker implantation due to prolonged CSNRT
10	8	DVT
11	1	TIA
12	2	Right groin hematoma
13	1	Transection femoral artery with subsequent AV fistula
14	1	Femoral AV fistula repair
15	2	Pseudoaneurysm/hematoma
16	5	Ablation for left atrial tachycardia
	6	CVA, multiple cerebellar infarcts
17	1	Atrial fib
18	4	CVA in patient with pre-existing cerebrovascular disease
19	4	Cholecystitis
20	1	Fever

All the adverse events above can be attributed to the procedure. The adverse events in two patients (*) could possibly be attributed to the use of the device for a rate of 2/250 or 0.8%.

Eight (8) patients died during the course of the study. The deaths were non-temporally related to the ablation procedure. Details regarding patient deaths are summarized below:

Days post ablation	Death summary
345	79 year old man with CHF, s/p CABG 1994, collapse at home in shower, in asystolic arrest when ambulance on scene, autopsy showed AMI and cardiac hypertrophy
53	41 year old man with dilated cardiomyopathy, sudden collapse at work 53 days post ablation, in fine VF was cardioverted to junctional rhythm without perfusion, degenerated to asystole, no autopsy performed
38	71 year old woman with history of a total knee replacement developed a pulmonary embolus 10 hours post a successful ablation procedure which was performed without anticoagulation. This large left pulmonary artery embolus was associated with bilateral pleural effusions and a small pericardial effusion. She was treated with heparin and coumadin. She also fell after the ablation procedure, prior to d/c and sustained a periprosthetic left femur fracture, during treatment and recovery she developed MRSA sepsis from a CVP line, and died from complications
214	73 year old man s/p MI, hypertensive, COPD. Did not have a successful ablation procedure. He had worsening respiratory symptoms 6 months post ablation, and was admitted to a nursing home under hospice care. Death was thought to be due to pre-existing respiratory disease.
59	73 year old woman with hypertension, CHF, on CPAP at night had abrupt

	onset of severe SOB, chest pain and cough 60 days post ablation. Taken to ER where she rapidly deteriorated to cardiopulmonary arrest 3 hours after onset. No clear reason for death documented.
40	52 year old man with history of PVD, CAD, MI 1990, end stage cardiomyopathy, cardiogenic shock one month prior to ablation. He underwent a successful right atrial ablation for typical atrial flutter on 6/16/00. He continued to have left atrial tachycardia and underwent a second ablation procedure on 6/21/00 during which he had multiple bilateral infarcts in the posterior cerebellum. His neurological exam improved but he was transferred to hospice care because of ongoing CHF. Cause of death was thought to be due to worsening CHF.
15 months	74 year old man developed staphylococcal SBE of the mitral valve more than one year post successful ablation procedure.
30	48 year old woman died after a complicated elective gastric bypass surgery procedure.

6. Statistical Analysis

The table below summarizes the safety and effectiveness of the device when compared to the control group OPC for safety, acute success, and long-term success.

Comparison of Endpoints between EPT-1000 XP™ System Study and OPC

Endpoint	OPC		EPT-1000 XP™ Study	
	%	One-sided 95% Confidence Bound ¹	% (N)	One-sided 95% Confidence Bound ¹
Acute Success	86%	80%	94% (235/250)	91.5% (lower bound)
Major Complications	3%	7%	8% (20/250)	10.8% (upper bound)
Six-Month Success	86%	80%	96% (145/151)	93.4% (lower bound)

¹Exact binomial using a commercially-available software package.

By comparing the lower bounds of the acute success (91.5% vs. 80%) and six-month success endpoints (93.4% vs. 80%), the results demonstrate that the EPT-1000 XP™ Cardiac Ablation System met the OPC for acute success and six-month success rates. As previously explained, although the device exceeded the upper bound of major complications, review of the specific events revealed that most events were not device-related; accordingly, the adverse event rate was acceptable.

EPT-1000 XP™ Cardiac Ablation Controller & Accessories 110V

Operator's Manual

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

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P/N:90067547-01 Rev A (4/03)

Spec: 90067747 Ver AA

Preface

Manual Conventions

The following naming conventions are used in the *EPT-1000 XP™ Cardiac Ablation Controller & Accessories Manual*:

The EPT-1000 XP™ Cardiac Ablation Controller & Accessories is referred to as the “System.” For a complete description of the System’s components, refer to Section 1, *System Description*.

- The EPT-1000 XP™ Cardiac Ablation Controller is referred to as the “Controller.”
- The Automatic Personality Module is referred to as the “APM.”
- The High Power Automatic Personality Module is referred to as the “XP APM.”

The Catheters are referred to as follows:

- Steerable Ablation Catheter with temperature measuring capability (thermistor): “Catheter (T°).”
- Steerable Ablation Catheter without temperature measuring capability: “Catheter (Non-T°).”
- Catheter information pertaining to both Catheter styles: “Catheter.”

General Information

The use of all components and accessories of the EPT-1000 XP™ Cardiac Ablation System is fully described in this Manual, except for the Steerable Ablation Catheters.

This Manual provides a description of the Controller, its controls and displays, and a sequence for its operation. In addition, it provides information relevant to the operation of the appropriate accessories with the The EPT-1000 XP™ only, as well as other information of importance to the user.

■ **Precaution** *Do not attempt to operate the System before thoroughly reading this Operator’s Manual. It is important that the equipment’s operating instructions be read, understood and followed. For future reference, retain this Manual in a convenient, readily accessible place.*

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1. System Description

The EPT-1000 XP™ Cardiac Ablation System (see Figure 1-1) consists of two principal subsystems:

- BSC Model #800XP Cardiac Ablation Controller (RF Generator)
- Catheter (T°) or Catheter (Non-T°) with Quick Connect Instrument Cables for connection to the EPT Model #822T High Power Automatic Personality Module or BSC Model #821T Automatic Personality Module

☒ **Note** Refer to Figure 1-2 for cable configuration.

One optional accessory is provided with the Controller:

- BSC Model 840 Footswitch

For system operation and power level access greater than 50 W/1 A, it is **mandatory** to use the XP APM. If accessing up to 100 W/2 A power levels, both an XPAPM and a special high power catheter must be used. The Footswitch usage is optional as the Controller can be operated directly from its front panel controls. The EPT-1000 XP™ Cardiac Ablation System is operated in conjunction with commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrodes, which are in compliance with ANSI/AAMI Standard HF-18.

☒ **Note:** When using special high power catheters with the EPT-1000 XP™ Controller, two DIP Electrodes are required.

The Catheter delivers RF power in a monopolar mode between its distal electrode and the large DIP Electrode(s). Detailed information regarding the Catheter is contained in the appropriate Directions For Use.

1-1 System Description

System Features

The EPT-1000 XP™ Cardiac Ablation System features the following:

- The Controller produces a continuous unmodulated radio frequency (RF) output at 500 kHz.
- The front panel displays the actual power output, tissue impedance, and if a Catheter (T°) is connected to the Controller, catheter tip temperature.
- The Controller measures RMS (Root Mean Square) voltage, RMS current, and actual power output by taking the average value of the product of voltage and current. (This reflects the effective heating power delivered to the tissue from the Catheter electrode tip. Impedance is calculated as RMS voltage divided by RMS current.)
- The amount and duration of RF power delivery is user-selectable, and if a Catheter

(T°) is connected, the desired tissue temperature or maximum tissue temperature is also user-selectable.

- The number of RF power deliveries is automatically counted for the physician.
- The XP APM provides RF filtering to allow continuous electrogram recording during RF power delivery via the catheter tip electrode.
- The XP APM allows for safe use of either standard or high power BSC ablation catheters.

Safety Features

The System's built-in safety features include automatic shutoff for the following conditions:

- If accessing up to 50 W of RF power and measured tissue impedance is less than 50 Ω .
- If accessing up to 100 W of RF power and measured tissue impedance is less than 25 Ω .
- If measured tissue impedance exceeds 300 Ω .
- If maximum voltage or current limits are exceeded.
- The Controller shuts off if the measured temperature exceeds 85°C for greater than 1 second with high power catheters and 95°C for greater than 1 second with standard catheters, or if measured temperature exceeds the upper temperature limit selected in the Power Control mode. This temperature is not the maximum tissue temperature. The recorded temperature may be up to 15°C different from the maximum tissue temperature. The temperature can be set up to 80°C for high power catheters.
- The Controller shuts off if the measured temperature exceeds the user-selected temperature setpoint by 5°C for greater than 4 seconds. This temperature is not the maximum tissue temperature.
- If greater than 1 A of current is delivered to either of the two DIP Electrodes connected to the XP APM, the Controller shuts off.

System Description 1-2

Control Modes

The Controller is capable of operating in two “control modes” (Power Control or Temperature Control).

Power Control

The Power Control mode is compatible with all defined Catheter types and allows selection of the quantity of RF power that is delivered by the Catheter. If using a Catheter (T°), the Controller delivers the set power unless the upper temperature limit is exceeded, which results in a reduction in the amount of power delivered.

Temperature Control

The Temperature Control mode is *only* available when using Catheter (T°) and allows selection of a desired tissue temperature.

The maximum amount of power to be delivered by the Catheter must be selected for both control modes (Power Control or Temperature Control).

☒ **Note:** When using the EPT-1000 XP

™ Cardiac Ablation Controller in the

Temperature Control mode, **ALWAYS** ensure that the TEMP LED on the Control Panel is illuminated.

The following table defines the power delivery protocol for both the Power Control and Temperature Control modes for the Controller with XP APM connected.

1-3 System Description

Table 1-1: Power Delivery Protocol
Catheter Type Maximum Maximum
Power Setting Current

3. Warnings, Precautions, and Adverse Reactions

Warnings for the Controller

Before operating, read these warnings carefully:

- The displayed temperature is not the maximum tissue temperature. Do not set the maximum temperature higher than 80°C .

- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:

- a) Retain temporary external sources of pacing available during ablation.

- b) Reprogram the pacing system temporarily to minimum output or 000 mode to reduce risk of inappropriate pacing.

- c) Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.

- d) Perform complete pacing system analysis on all patients after ablation.

- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.

- The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of components with unprotected male pin connectors must exercise extreme caution during device set-up to prevent patient or operator injury.

Unused pins should be secured so that they do not inadvertently touch other equipment or surfaces. Never insert pins into MAINS outlets or into any equipment other than systems providing patient electrical isolation in accordance with EN-60601.

- The APM or XP APM output labeled recorder must only be connected to a medically isolated recorder.

- Grounding reliability can only be achieved when the power supply cord is connected to a receptacle marked Hospital Only or Hospital Grade.

- If a “Booker Box” device is used, it should be used with a DIP electrode that is separate from the DIP electrode used by the Controller.

3-1 Warnings, Precautions, and Adverse Reactions

Precautions

Observe these precautions, before using the System:

- Do not attempt to operate the BSC Cardiac Ablation System before thoroughly reading the EPT-1000 XP™ Cardiac Ablation Controller Operator’s Manual.

- When using high power catheters, it is required that two Disposable Indifferent Patch Electrodes be used as the ablation return electrodes or skin burns may result.

- The use of non-EPT approved extension cables may alter the performance of the RF generator and render it out of specification.

- Due to the larger surface area of the catheter’s distal tip, coagulum formation may not result in a sudden impedance rise. The catheter should be removed after each line of block and the distal tip of the catheter cleaned to minimize coagulum.

- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications.

- The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children.
 - The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
 - Read and follow the Disposable Indifferent (Dispersive) Patch (DIP) Electrode manufacturer's instructions for use; the use of DIP Electrodes which meet or exceed ANSI/AAMI HF-18 requirements is required.
 - Placement of a DIP electrode on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.
 - The Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the Catheter and DIP Electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
 - Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP Electrode or failure of an electrical lead. *Do not increase power before checking for obvious defects or misapplication.*
 - The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the ablation site.
 - Electromagnetic interference (EMI) produced by the Controller during the delivery of RF power may adversely affect the performance of other equipment.
 - Regularly inspect and test re-usable cables and accessories.
- Warnings, Precautions, and Adverse Reactions 3-2

4. *Unpacking the Controller*

Unpacking

The Controller's shipping carton contains the components identified below:


- ☐ 1 - Controller
- ☐ 2 - EPT-1000 XP™ Cardiac Ablation System Operator's Manuals

The following System components are individually shipped separately:

- ☐ 1 - Footswitch
- ☐ 1 - XP APM with Quick Connect Connectors
- ☐ 1 - Interconnect Cable for XP APM to EGM Equipment
- ☐ 1 - Quick Connect Temperature Instrument Cable
- ☐ 1 - Quick Connect Non-Temperature Instrument Cable
- ☐ 2 - Ground Pads (Disposable Indifferent Patch Electrodes)

To unpack the System, follow these steps:

1. Unpack the Controller and accessories carefully and inspect for damage.
2. Notify the carrier immediately if the shipment carton is damaged.
3. Verify that the items listed above are received.

 **Call BSC for Service** If there are any discrepancies, notify BSC. See Section 7, *Service and Maintenance* of the Operator's Manual.

4. Read Section 6, *Operational Sequence* in this Manual very carefully and follow the installation and setup instructions.

Repackaging the Controller

When the Controller requires service or transfer to other location, use the original shipping carton and packing materials to repack and ship the Controller.

For shipping, disconnect the APM or XP APM and Footswitch. Place all the components into the locations reserved for these units in the carton.

4-1 Unpacking the Controller

5. Controls and Displays

Front Panel

The operator controls for the EPT-1000 XP™ Cardiac Ablation Controller are located on the front panel of the Controller. The buttons on the Controller's front panel allow the user to control the operation of the Controller. The lights/LEDs on the front panel show the Controller's status and/or report error conditions.

This section describes the operator controls on the front panel shown in Figure 5-1.

Figure 5-1: Controller Front Panel

Controls and Displays 5-1
TEMPERATURE (°C) IMPEDANCE () TIME (S)

COUNTER CLEAR
RF POWER
CONTROL
ISOLATED PATIENT
CONNECTOR
CONTROL
POWER TEMP
CALIBRATION
MAINS
POWER (W)
Power
Panel
Temperature
Panel
Impedance
Panel
Time
Panel
Control
Panel
Calibration
Panel
Counter
Panel
RF Power
Control Panel
Isolated Patient
Connector
Mains
Display
CARDIAC ABLATION CONTROLLER
EPT-1000 XP

CONTROL Panel

CONTROL Indicator LEDs

The control mode of the Controller is indicated by either of two green LEDs (POWER or TEMP) on the CONTROL Panel (see Figure 5-2). When the Controller is initially powered on, one of the green LEDs displays the control mode which depends on the type of Catheter connected to the Controller.

If a Catheter (T°) is connected, the Controller automatically switches to the Temperature Control mode when initially powered on, as indicated by the flashing green TEMP LED. If it is desirable to operate the Controller in the Power Control mode while using a Catheter (T°), pressing the CONTROL Button (see Figure 5-2) changes the control mode to Power Control, as indicated by the flashing green POWER LED.

If a Catheter (Non-T°) or no Catheter is connected, then the Controller automatically switches to the Power Control mode, when initially powered on, as indicated by the flashing green POWER LED.

⌘ **Note** POWER, TIME, and TEMPERATURE setpoints all reset to default values whenever a Catheter (T°) is disconnected and reconnected, or when a switch is made between control modes (Power Control to Temperature Control or vice versa). During RF power delivery, the control mode cannot be changed.

Figure 5-2: CONTROL Panel Indicator LEDs and Button

5-2 Controls and Displays

Control
Panel
Power
LED
Temp
LED
Control
Button

CONTROL

POWER TEMP

CONTROL Button

The Controller is capable of operating in Power Control or Temperature Control mode. Press the CONTROL Button to toggle (or change) to a new control mode, as indicated by a flashing LED.

The Power Control mode is compatible with Catheter (T°) and Catheter (Non-T°) and allows selection of the quantity of RF power that is delivered by the Steerable Ablation Catheter (see Table 5-1). It also allows selection of an upper temperature limit from 55°C to 85°C for XP catheters, 95°C for standard catheters (the default value).

The Temperature Control mode is *only* compatible with Catheter (T°) and allows selection of a desired tissue temperature. The maximum amount of power to be delivered by the Catheter, from a value of 0 W to a maximum of either 50 or 100 W depending on catheter type, must also be selected in the Temperature Control mode (see Table 5-1). If insufficient power is selected, the desired tissue temperature may not be achieved.

Catheters are designed to transmit three distinct quantities of RF power, based on their electrode size, internal construction and intended use. The maximum amount of power the Catheters can access is limited by the control mode and catheter type as follows:

☒ **Note:** Access to greater than 50W of power requires the use of appropriately coded (high power) catheters and the XP APM.

Controls and Displays 5-3

Table 5-1: Maximum Amount of Power Output for Catheters

Control Modes

**Catheter Type APM Type Power Control Temperature Control
(W) (W)**

Catheter (Non- APM or XPAPM 50 N/A T°)

Catheter (T°) APM or XPAPM 50 50 High Power) XP APM 100 100

Catheter (T°)

POWER Panel

POWER Display

The POWER Display (see Figure 5-3) shows the RF power output in Watts. The available power output ranges are dependent on the catheter type and the control mode. Ranges are from a value of 0 Watt to the maximum amount of power output (see Table 5-1).

When the Controller is initially powered on, the POWER Display indicates the default power setpoint of 0 Watt. After the user sets the power setpoint and presses the RF POWER CONTROL Button, the display changes from the setpoint value and begins displaying the actual power output the Catheter delivers to the tissue.

In the Power Control mode, the Controller adjusts its output to maintain the measured power at the power setpoint, and in the Temperature Control mode, the Controller adjusts its output to maintain the measured temperature at the temperature setpoint. In the Temperature Control mode, measured power may be lower than the power setpoint value, depending on the measured tissue temperature and/or tissue impedance. When RF power is discontinued (DONE operational mode), the last measured value of RF power delivered remains on the display, flashing at 1-second intervals.

Figure 5-3: POWER Display and Buttons

5-4 Controls and Displays

Power
Panel Power
Display
Power
Increase
Button
Power
Decrease
Button
POWER (W)

POWER ⏏/⏏ Buttons

The POWER ⏏/⏏ (increase/decrease) Buttons select the desired level of delivered RF power for the Power Control mode, or the maximum amount of RF power available for the Temperature Control mode.

For instructions on how to select the level of delivered RF power, see the section *Selecting the Power Output* on page 6-10.

TEMPERATURE Panel

TEMPERATURE Display

The TEMPERATURE Display (see Figure 5-4) shows the temperature setpoint (desired tissue temperature) in degrees Centigrade. *This feature is only available if a Catheter (T°) is connected to the Controller.*

Figure 5-4: TEMPERATURE Display and Buttons

Controls and Displays 5-5

Temperature
Panel
Temperature
Display
Temperature
Increase
Button
Temperature
Decrease
Button

(C) TEMPERATURE

Table 5-2 lists all possible temperature display readings under specific operating conditions. Refer to the instructions specified in the table for additional information.

5-6 Controls and Displays

Table 5-2: Summary of TEMPERATURE Display Readings

Catheter Type Control Mode TEMPERATURE Display Readings

Catheter (T°) Temperature • At initial power on, display reading is 30°C.

Control Mode • After setting temperature setpoint per instructions, display indicates desired tissue temperature. (Refer to instructions on page 6-12, *Selecting Temperature When Using the Catheter (T°) in TEMPERATURE Control Mode.*)

- In ON or CALIBRATE operational modes, display indicates measured catheter tip temperature.
- In ON operational mode:
 - If the temperature is within 20°C - 120°C range, the measured temperature displays.

– If the measured temperature is below 20°C, the message

“LO” displays.

– If the measured temperature is above 120°C, the message

“HI” displays.

- In DONE operational mode: When RF power is discontinued, the last measured value of temperature is shown on the display, flashing at 1-second intervals.

Catheter (T°) Power Control • In READY mode, display reading is 85°C for high power Mode catheters and 95°C for standard catheters.

- In ON or CALIBRATE operational modes, display indicates measured catheter tip temperature.

- In ON operational mode:

- If the temperature is within 20°C - 120°C range, the measured temperature displays.

- If the measured temperature is below 20°C, the message “LO” displays.

- If the measured temperature is above 120°C, the message “HI” displays.

- In READY mode, upper temperature limit can be selected.

After setting temperature setpoint per instructions, display indicates desired catheter tip temperature. (Refer to instructions on page 6-13, *Selecting Temperature When Using the Catheter (T°) in POWER Control Mode.*)

- When RF power is discontinued, the last measured value of temperature is shown on the display, flashing at 1-second intervals.

Catheter (Non-T°)* N/A • Display shows three dashes (---)

* Temperature Control is not accessible for this Catheter.

☒ **Note:** In Power Control mode only, when the measured catheter tip temperature decreases to a value that is below the upper temperature limit, the Controller resumes delivery of RF power at a value that is 50% of the power which caused the upper temperature limit to be exceeded. If the upper temperature limit is exceeded a second time, the Controller immediately ceases delivery of RF power and displays an error code indicating that the upper temperature limit has been exceeded a second time. It is recommended that if this error condition arises, the power level should be decreased to prevent the upper temperature limit from being exceeded. The Controller can be placed into the READY mode by depressing the RF POWER CONTROL Button, which allows adjustment of Controller parameters such as RF power, upper temperature limit, etc.

TEMPERATURE ▲/▼ Buttons

The TEMPERATURE ▲/▼ (increase/decrease) Buttons select the temperature that the Controller attempts to achieve during RF power delivery. In Temperature Control mode, the Controller automatically adjusts power, within the user-selected upper power limit, to achieve the desired tissue temperature. In Power Control mode, the Controller automatically decreases RF power to the Catheter if this value of user-selected upper temperature limit is exceeded. For instructions on how to select the temperature setpoint, see the section *Selecting the Desired Tissue Temperature* on page 6-12.

IMPEDANCE Panel

IMPEDANCE Display

The IMPEDANCE Display (see Figure 5-5) shows the measured impedance value in Ω (1 Ω resolution). When the Controller is initially powered on, the display shows three dashes “---”, indicating that no measurement is being made. As soon as RF power is delivered by pressing the RF POWER CONTROL Button or the Footswitch, the Controller begins to measure impedance. Because this display reflects the actual tissue impedance, the value shown may fluctuate slightly, depending on the quality of the electrode/tissue interface, but

should remain relatively stable throughout power deliveries. For a summary of the impedance ranges, see Table 6-2 in section *Turning the RF Power Delivery "ON"*.

Controls and Displays 5-7

When RF power is discontinued, the last measured value of impedance remains on the display, flashing at one second intervals. If the Controller is placed into the CALIBRATION mode (by depressing the CALIBRATION Button) and if a Catheter has been positioned within the heart, then the Controller delivers 1 Joule of energy which allows a single measurement of impedance, and continuously displays the value of impedance measured. When either the CALIBRATION or RF POWER CONTROL Buttons are depressed, the Controller returns to the READY mode and the IMPEDANCE Display returns to three dashes "___".

Figure 5-5: IMPEDANCE Display

5-8 Controls and Displays

TIME Panel

TIME Display

The TIME Display (see Figure 5-6) shows the user-selected duration (in seconds) of RF power delivery to the Catheter. When the Controller is initially powered on, the TIME Display reads zero. After the user sets the duration and presses the RF POWER CONTROL Button, the displayed value changes to zero and initiates counting upward at 1-second intervals until the preset time limit is reached (or the RF POWER CONTROL Button is actuated a second time or the Footswitch is released), stopping RF power delivery. If RF power delivery is stopped before the preset maximum duration has been reached, actual duration of RF power delivery is displayed, flashing at 1-second intervals.

TIME ⏏/⏏ Buttons

The TIME ⏏/⏏ (increase/decrease) Buttons select the maximum duration of each RF power delivery. The range of times available is 1 to 120 seconds in increments of one.

⏏ **Note:** These buttons are inoperative during RF power delivery.

For instructions on how to select the duration of RF power delivery, see the section *Setting the Time Control* on page 6-13.

Figure 5-6: TIME Display and Buttons

Controls and Displays 5-9

TIME (S)

Time

Panel

Time

Display

Time

Increase

Button

Time

Button

Decrease

COUNTER Panel

COUNTER Display

The COUNTER Display (see Figure 5-7) automatically counts and displays each delivery of RF power. When the Controller is initially powered on, the display clears and reads zero. The range of values available is 0 to 99 in increments of one.

CLEAR (Counter) Button

The CLEAR Button clears the COUNTER Display (Figure 5-7) to zero and allows the user to keep an accurate count of the number of RF power deliveries to the patient. Press this button before starting initial RF power application on a patient.

Figure 5-7: COUNTER Display and Clear Button

RF POWER CONTROL Panel

RF POWER CONTROL Button/Light

The RF POWER CONTROL Button (see Figure 5-8) controls the three operational modes of the Controller:

- READY mode - This mode allows the ablation parameters to be adjusted.
- ON mode - This mode is the Controllers' state during the delivery of RF power.
- DONE mode - This mode defines the system state after cessation of RF power delivery.

⌘ **Note:** This button can also be used for exiting the CALIBRATION or Error modes and returning the Controller to the READY mode.

When the Controller is initially powered on, the RF POWER CONTROL Light flashes, indicating the Controller is in the READY mode and prepared for RF power delivery.

Press the yellow RF POWER CONTROL Button once to place the Controller into the ON mode and allow the Catheter to transfer RF power to the tissue. To alert the user, this button is backlit with a light which is ON during the delivery of RF power (RF Power ON mode), and OFF when RF power delivery stops (DONE mode).

5-10 Controls and Displays

Counter

Panel

Clear

Button

Counter

Display

COUNTER CLEAR

If the Controller is in the Temperature Control mode, a test of the temperature sensor functionality is made prior to delivery of RF power. If a faulty temperature sensor is detected by the Controller, which can be caused by the temperature sensor indicating a temperature outside the operating range of 20°C to 43°C, or a short or open in the temperature measurement circuit, the Controller does not enter the RF Power ON mode. It enters an Error mode, indicating a faulty temperature measuring circuit has been detected or the temperature is outside the operating range. To exit the Error mode, depress the RF POWER CONTROL Button, which returns the Controller to the READY mode.

Figure 5-8: RF POWER CONTROL Panel and Button/Light

CALIBRATION Panel

CALIBRATION Button

Pressing the CALIBRATION Button (see Figure 5-9) places the Controller into the CALIBRATION mode which performs the following functions:

- Approximately 1 Joule of energy is delivered to the tissue which is used to make a single measurement of tissue impedance. This value is continuously displayed on the front panel.
- The catheter tip temperature is continuously monitored and displayed on the front panel. This allows assessment of the temperature measuring function of the Catheter (T°). If this value differs significantly from the normal body temperature of 37°C, the Catheter (T°) should be removed and replaced with another Catheter (T°).
- A zero to one volt square-wave signal representing a minimum-to-full-scale signal is transmitted from each of the rear panel analog outputs (for calibration of an optional recorder). This square-wave calibration signal is transmitted continuously to the rear panel analog output ports.

Controls and Displays 5-11

RF POWER

CONTROL

RF Power

Control

Panel
RF Power
Control
Button/Light

All of the above functions continue to operate as described above until either the CALIBRATION or RF POWER CONTROL Buttons are pressed again. Pressing either of these buttons causes the Controller to return to the READY mode. The minimum-to-full scale values for the individual analog outputs are shown in Table 5-3.

The CALIBRATION LED illuminates when a calibration signal is transmitted to the analog output ports. The calibration signal automatically discontinues if the RF POWER CONTROL Button or the Footswitch is pressed.

Figure 5-9: CALIBRATION Panel and Button/LED

Isolated Patient Connector

The ISOLATED PATIENT CONNECTOR (see Figure 5-1) provides for connection of the APM (either APM or XP APM) to the Controller. The connector has a screw-on/locking mechanism for secure cable installation. The APM Patient Cable must be installed in the ISOLATED PATIENT CONNECTOR before the Controller delivers any RF power. This cable uses a circular connector that is keyed for proper alignment.

MAINS (Power “ON”) Display

The MAINS Display (see Figure 5-1) indicates that the power switch (see Figure 5-10) located on the rear panel is ON (“1” position) and the Controller is plugged into an electrical outlet.

5-12 Controls and Displays

CALIBRATION
Calibration
Panel
Calibration
Button
Calibration
LED

Table 5-3: Individual Analog Outputs

Power 0.0 - 1.0 volt corresponds to 0 - 100 W
Impedance 0 - 1.0 volt corresponds to 0 - 300
Temperature 0.0 - 1.0 volt corresponds to 20° - 120°C

Rear Panel

This section describes the output ports and power controls on the rear panel shown in Figure 5-10.

Figure 5-10: Controller Rear Panel

POWER Switch

The power switch (rocker switch) on the rear panel powers the Controller ON (“1” position) or OFF (“0” position).

Analog Outputs

There are 4 analog output ports (see Figure 5-10), which are labeled as follows: RF POWER, IMPEDANCE, TEMPERATURE, and SPARE.

Controls and Displays 5-13

•
RF POWER
ANALOG OUTPUT SPEAKER
FOOT SWITCH RS-232
MAIN
FUSES
WARNING
RISK OF FIRE.
REPLACE FUSE
AS MARKED.
WARNING
RISK OF FIRE.
REPLACE FUSE
AS MARKED.
OUTPUT POWER 150W

OPERATING FREQUENCY 500KHz
IMPEDANCE TEMPERATURE SPARE VOLUME
CAUTION: DO NOT OPEN
ELECTRICAL SHOCK HAZARD

100-120V
3A 50/60 Hz
220-240V
1.5A 50/60 Hz

AUX
MAINS

100-120V
1A 50/60 Hz
220-240V
500mA 50/60 Hz

100-120V
1A 50/60 Hz

Power

Switch

Analog

Outputs

Power

Cord

Mains

Fuse

Holder

Fuse

Holders(2)

Footswitch

Cable

Connector

Volume

Control

Knob

Serial

Port

Auxiliary

Power

Outlet

Ground

Stud

CAUTION: THE TOTAL SYSTEM
CHASSIS RISK CURRENT SHOULD NOT
EXCEED 100mA

ATTENTION: LE COURANT DE RISQUE
TOTAL ADMISSIBLE AU CHASSIS NE
DOIT PAS DEPASSER 100mA.

AUX
FUSES

Power Analog Output

RF POWER - This output port provides direct connection to an electrically isolated general-purpose recorder or monitor, satisfying the requirements of EN-60601, using a standard BNC connector to facilitate recording of the RF power output during delivery of RF power.

Impedance Analog Output

IMPEDANCE - This output port provides direct connection to an electrically isolated general-purpose recorder or monitor, satisfying the requirements of EN-60601, using a standard BNC connector to facilitate recording of the tissue impedance during delivery of RF power.

Temperature Analog Output

TEMPERATURE - This output port is active only when a Catheter (T°) is in use. It provides direct connection to an electrically isolated general-purpose recorder or monitor, satisfying the requirements of EN-60601, using a standard BNC connector to facilitate recording of the Catheter (T°) measured catheter tip temperature during delivery of RF power.

Spare

SPARE - This output port is not in use at this time.

Power Cord

The Power Cord is "Hospital Grade" and must be installed at an AC electrical wall outlet designated "Hospital Grade" or "Hospital Only."

MAINS Fuse Holder

Housing for AC fuse. (See Controller rear panel for appropriate type of fuse.)

Fuse Holders (2)

Housing for AC fuses. (See Controller rear panel for appropriate type of fuse.)

Footswitch Cable Connector

This connector is polarized for connecting the Footswitch Cable.

5-14 Controls and Displays

Volume Control Knob

This knob provides the user with volume control for the audio signal that accompanies RF power delivery. If no audio tone is heard, check the knob to determine if the volume level has been adjusted too low.

Serial Port

This port is labeled “RS-232.” It provides for computer interface to BSC approved accessory computers only.

Auxiliary Power Outlet

This outlet is labeled “Auxiliary Power Outlet.” It provides for future optional Boston Scientific approved accessories only.

Ground Stud

Protective Earth Ground stud (chassis ground).

Controls and Displays 5-15

Accessories

Footswitch

An easy-to-use Footswitch (see Figure 1-1) can alternatively be used to provide ON/OFF control of the RF power delivery. The connecting cable’s 10-ft length allows the user to stand at the catheterization table near the patient without requiring another person for starting/stopping RF power delivery. The Footswitch functions similarly to the RF POWER CONTROL Button except that the user must continuously hold the Footswitch down for RF power to be delivered. The RF power delivery is immediately terminated when the user’s foot is lifted off the Footswitch. Use only the BSC Model 840 Footswitch, which is rated IPX8 (continuous immersion).

High Power Automatic Personality Module (XP APM)

The XP APM provides RF filtering to allow continuous electrogram recording during RF power delivery via the catheter tip electrode. Additionally, the XP APM allows for safe use of either standard or high power EPT ablation catheters. The XP APM passes RF energy (at 500 kHz) from the Controller to the patient via the catheter and one or two DIP Electrodes. The maximum power delivered depends on the configuration of the attached catheter. The XP APM detects the presence of a high power catheter and enables the Controller to deliver RF power up to 100 W. If a standard catheter is detected, the Controller is not able to deliver power greater than 50W.

The Module connections are as follows (see Figure 5-11):

- One 9-pin Quick Connect Connector labeled “CATHETER” for attaching the Quick Connect Instrument Cable to the catheter.
- One 6-pin Recorder Connector labeled “RECORDER” for attaching the XP APM/EGM Interconnect Cable to the recording equipment.
- Two male 2-pin connectors labeled “INDIFFERENT ELECTRODE” for attaching the two DIP Electrodes.

☒ **Note:** If greater than 1 A of current is delivered to either of the two DIP Electrodes, the System shuts down.

For additional information on the XP APM, refer to *Table 8-1: System Specifications* in Section 8.

5-16 Controls and Displays

Automatic Personality Module (APM)

The APM (See Figure 5-12) provides automatic switching from electrogram recording to RF power delivery via the catheter tip electrode. The APM has the following connections:

- The Catheter is connected to the APM utilizing the Quick Connect or Instrument Cable. There is a Quick Connect fitting on the front panel of the APM for connection to the Quick Connect Instrument Cable.
- There is a Quick Connect fitting on the side of the APM for connection to the APM/EGM Connector Cable.

☒ **Note:** The Quick Connect Instrument Cable and APM/EGM Connector Cable fittings have different pin patterns to prevent cable assembly error.

- The DIP Electrode is connected to the male 2-pin connector (labeled “INDIFFERENT ELECTRODE”) on the APM front panel.

Controls and Displays 5-17

Figure 5-11: High Power Automatic Personality Module with Quick Connect

5-18 Controls and Displays

CATHETER

Front Panel

Top View

CARDIAC ABLATION SYSTEM

XP AUTOMATIC PERSONALITY MODULE

CATHETER

RECORDER

EP Technologies, Inc.

X 2

Side Panel

!

ELECTRODES INDIFFERENT

INDIFFERENT ELECTRODES

EPT-1000 XP APM

FOR USE WITH EP TECHNOLOGIES

CARDIAC ABLATION SYSTEM ONLY!

RECORDER

Figure 5-12: Automatic Personality Module with Quick Connect

Controls and Displays 5-19

6. Operational Sequence

Initial Installation

Follow the instructions in this section carefully to prepare the System for operation:

- 1.** Connect the Controller Power Cord plug into a properly grounded AC electrical outlet designated “Hospital Grade” or “Hospital Only.”

⚡ **Precaution:** Never use an outlet without a grounding connection.

- 2.** Position the Controller for easy viewing of its front panel displays.

- 3.** Install the APM (either APM or XP APM) Patient Cable to the ISOLATED PATIENT CONNECTOR socket on the Controller front panel by carefully lining up the connector pins with the socket. Push the connector firmly into the socket; then secure in place by rotating the locking ring in a clockwise direction.

⚡ **Note:** Do not twist the APM Patient Cable connector while inserting or removing it from the Controller ISOLATED PATIENT CONNECTOR socket or the connector pins may be damaged.

6-1 Operational Sequence

Figure 6-1: Connecting the APM to the Controller Front Panel

4. To disconnect the APM (either APM or XP APM) from the Controller, rotate the locking ring counter clockwise to unlock; then grasp the connector and gently pull it out of the socket.

⚠ **Note:** Do not twist the APM Patient Cable connector while inserting or removing it from the Controller ISOLATED PATIENT CONNECTOR socket or the connector pins may be damaged.

⚠ **Precaution:** Never disconnect the APM by pulling on the cable.

5. For Optional Patient Monitor Equipment Installation only, follow these instructions:

a) Use the APM/EGM Interconnect Cable to connect the APM (either APM or XP APM) to optional recording equipment (see Figure 6-2).

b) Plug in the Quick Connect fitting from the APM/EGM Interconnect Cable into the connector located on the APM side panel labeled “RECORDER” and plug the opposite end of this cable into isolated recorder inputs.

Operational Sequence 6-2

Figure 6-2: Connecting the APM to the Recording Equipment

6. Position the APM (either APM or XP APM) near the table where the procedure is to be performed. The System may only be connected to recording systems providing patient electrical isolation in accordance with EN-60601.

7. Install the Catheter Quick Connect Instrument Cable fitting into the APM (either APM or XP APM) front panel fitting labeled “CATHETER.”

6-3 Operational Sequence

Figure 6-3: Connecting the Catheter to the XP APM Front Panel

8. Install one DIP electrode if using an APM or 2 DIP electrodes if using an XP APM and a high power catheter into the INDIFFERENT ELECTRODE receptacle(s) located on the APM front panel (see Figure 6-4) as follows:

a) Read the manufacturer’s manual before installing the DIP Electrode pads.

b) Gently push each DIP Electrode fitting straight and firmly into place.

c) To disconnect a DIP Electrode, grasp the DIP Electrode fitting and gently pull it out from the APM Indifferent Electrode receptacle.

⚠ **Precaution:** Do not disconnect a DIP Electrode Connector by pulling on its cable.

d) Before use, it is important to check the DIP Electrode(s) for damage to the sealed foil package. Exposure to air, due to a damaged package, could cause the DIP Electrode(s) to become dry and limit their grounding capability.

e) Be sure the pads are moist and sticky to the touch before placing on the patient.

⚠ **Precaution:** Do not attempt to relocate the patient grounding pad after initial application. Electrode gel is NOT required and should NOT be used.

f) The DIP Electrode(s) should be placed on a well-vascularized, convex skin surface that is in close proximity to the ablation site (left upper quadrant of the back is suggested unless the patient’s scapula is especially prominent or patient is extremely thin). Other possible locations are the upper arm or left flank area. Avoid scar tissue, bony prominence, adipose tissue, or any areas where fluid may pool. Shave, clean, and dry the application site as needed. Check for wrinkles or folds when applying the pad as these decrease conductivity.

Operational Sequence 6-4

CATHETER
2 X
INDIFFERENT ELECTRODES
**Quick Connect
Instrument Cable
Catheter**

Figure 6-4: Connecting the Disposable Indifferent Patch Electrodes

Connector on the Controller rear panel (see Figure 6-5). Carefully push the cable connector into the FOOTSWITCH connector until it is seated firmly in place.

10. Position the Footswitch to allow easy access by the physician.

11. The System is now ready to record electrograms prior to and during delivery of RF power.

1. Turn the Controller ON by pressing the power switch (to the “1” position) located in the power input module on the Controller rear panel (see Figure 6-6).

⌘ **Note:** The connection between the APM (either APM or XP APM) and Controller is not required to complete the initial self-test.

[illegible]

Cable Connector

✘ **Call BSC for Service** A second self-test failure is indicative of a Controller malfunction and should be referred to BSC/EPT for service See Section 7, Service and Maintenance of the Operator's Manual. The Controller does NOT operate unless the initial self-test has been successfully completed.

The Ready mode is designed for setting the desired parameters for RF power delivery. It is automatically initiated after completion of a successful Controller self-test. Ready mode is indicated by a flashing RF POWER CONTROL Button on the Controller front panel;

TEMPERATURE, IMPEDANCE, TIME, and COUNTER Displays are continuously lit. Values displayed when the Controller is first initialized are zero in the POWER, TIME, and COUNTER Displays and dashes (---) in the IMPEDANCE Display. (Refer to Figure 5-1 for the location of displays and buttons.)

Controller in Temperature Control Mode - Catheter (T°) Connected

If a Catheter (T°) is connected, the TEMPERATURE Display shows one of two values depending on the control mode. When the Controller is initially powered on and a Catheter (T°) is connected, the TEMPERATURE Display indicates 30°C, since the Controller is automatically entered into the Temperature Control mode. The user must enter the desired catheter tip temperature, the maximum power that the Controller can deliver to achieve the desired temperature, and the ablation time before RF power delivery.

6-7 Operational Sequence

**MAINS
Power Switch
Power Input
Module**

Press Power Switch to "1" position.

Controller in Power Control Mode - Catheter (T°) Connected

If the control mode is manually changed to Power Control, by pressing the RF POWER CONTROL Button, the TEMPERATURE Display indicates 85°C with high power catheters, and 95°C with standard catheters during the READY mode of the Controller, indicating the upper temperature limit at which the Controller continues to deliver set power.

Controller in ON or CALIBRATE Operational Modes - Catheter (T°) Connected

When the Controller is in either the ON or CALIBRATE operational modes, the TEMPERATURE Display indicates "LO" if the measured temperature is less than 20°C, "HI" if temperature is greater than 120°C; otherwise, it shows the measured temperature (see Figure 6-7).

Figure 6-7: ON or Calibrate Mode - Catheter (T°) Connected

Catheter (Non-T°) or No Catheter Connected

If a Catheter (Non-T°) or no Catheter is connected, the display shows "---" (Figure 6-8).

Operational Sequence 6-8

*Measured
Temperature
Reading*

(C) TEMPERATURE

Figure 6-8: Ready Mode, Initialization - Catheter (Non-T°) Connected

Calibrating the Controller Analog Outputs for the Recorder

Each time the Controller is powered on, the analog outputs (see Figure 5-10) should be placed in the CALIBRATION mode to verify that the optional strip chart recorder and/or monitor are calibrated correctly, if used.

To perform calibration of the Controller analog outputs, follow these steps:

- 1.** Check that all connections to the analog outputs are secure.
- 2.** Ensure that the recorder/monitor is powered on and functioning properly.
- 3.** Ensure the recorder satisfies the requirements of EN-60601 prior to connection to Controller analog outputs.
- 4.** To calibrate with the analog outputs, press the CALIBRATION Button (Figure 6-9) at the Controller front panel. This generates a minimum-to-full-scale (0.0 to 1.0 volt) continuous square-wave calibration signal which is sent continuously and simultaneously to each of the

analog outputs (until the CALIBRATION Button is pressed again or until the RF POWER CONTROL Button or footswitch is pressed).

6-9 Operational Sequence

Temperature

Display

(C) TEMPERATURE

Figure 6-9: Calibrating the Controller Analog Outputs

5. With the Controller in the READY mode, analog output calibration can be repeated or checked at any time by repeating the steps identified in steps 1 through 3 above.

6. When RF power is delivered, the analog signals correspond to the Controller's measured power, temperature, and impedance values.

Selecting the Control Mode

The Controller is capable of operating in Power Control or Temperature Control mode.

Control mode selection is made via the CONTROL Button. (For complete description of the CONTROL Button, see *CONTROL Panel* in Section 1.)

To select the proper control mode, follow these steps:

1. Ensure that the Controller is in the READY mode.

⌘ **Note:** The control mode can only be changed when the Controller is in the READY mode.

2. Press the CONTROL Button to select the appropriate control mode. The CONTROL Indicator LEDs display the selected mode.

Operational Sequence 6-10

Calibration

Button

COUNTER CLEAR
RF POWER
CONTROL
CALIBRATION
MAINS

Selecting the Power Output

To deliver RF power, it is necessary to select a Controller power output. This is true for both Temperature Control mode and Power Control mode.

☒ **Note:** Use Lower Power First - Begin by using lower power (50W) when delivering RF energy. Monitor the temperature reading to determine if pre-set temperature is achieved. If not, gradually increase the power output to increase tissue heating. If the created lesion is unsuccessful or inadequate, incrementally increase the power output with successive ablation attempts to minimize the potential for thrombus formation and/or inadvertent damage to cardiac tissues.

Controller in Temperature Control Mode - Catheter (T°) Connected

The Controller is automatically entered into the Temperature Control mode and the RF power setpoint is the maximum amount of power that the Controller can access to achieve the desired catheter tip temperature. If the RF power setpoint is equal to or greater than the amount of power necessary to achieve the desired catheter tip temperature, then the Controller supplies the appropriate amount of power to achieve the temperature setpoint.

The Controller only supplies as much RF power as necessary to achieve the desired catheter tip temperature. If the RF power setpoint is less than the amount of power required to achieve the desired catheter tip temperature, then the Controller may not be capable of achieving the desired catheter tip temperature and thus the measured temperature is less than the desired catheter tip temperature.

Controller in Power Control Mode - Catheter (Non-T°) or Catheter (T°) Connected

If a Catheter (Non-T°) or Catheter (T°) is connected, and the Controller is placed into the

Power Control mode, then the RF power setpoint corresponds to the actual amount of power that is delivered to the tissue, unless the upper temperature limit is exceeded, in which case, the Controller reduces and/or ceases delivery of set power.

Controller in Power Control Mode - Catheter (T°) Connected

If using a Catheter (T°) with the Controller in the Power Control mode, the TEMPERATURE Display shows 85°C when the Controller is in the READY mode and displays measured temperature when the Controller is in the ON, CALIBRATE, and DONE operational modes.

6-11 Operational Sequence

Selecting the RF Power Setpoint

To set the RF power setpoint (in W), follow these steps:

- 1.** Press the appropriate POWER (▲/▼) Button to increase or decrease the RF power setpoint by 1 W.
- 2.** To scroll rapidly to the desired power setpoint, depress and hold the appropriate POWER (▲/▼) Button down.
- 3.** Release the POWER (▲/▼) Button when the POWER Display shows the appropriate RF power setpoint.
- 4.** During RF power delivery (RF Power ON mode), the power setpoint can be adjusted in 1-W increments to provide better control during the procedure by pressing the appropriate POWER (▲/▼) Button. When the button is released, the POWER Display returns to showing the current value of measured power.
 - Holding the POWER ▲ Button down while RF power is being delivered (RF Power ON mode) does NOT cause the power setpoint to scroll as it does when the Controller is in the READY mode.
 - Holding the POWER ▼ Button down while RF power is being delivered (RF Power ON mode) causes the power setpoint to scroll at a greater rate than it does when the Controller is in the READY mode.

Selecting the Desired Tissue Temperature

For ablation procedures involving automatic temperature control, it is recommended that the operator initially select a lower set temperature range (from 55°C to 70°C). The operator should consider a lower initial set temperature to avoid excessive thermal damage to tissue, or collateral damage to adjacent tissue not intended for ablation, particularly in areas where high blood flow and correspondingly high convective cooling may be present.

☒ **Note:** The displayed tissue temperature may be significantly lower than the maximum tissue temperature, which typically occurs at a depth of a few millimeters. The displayed catheter tip temperature is measured at the electrode-tissue interface and may be influenced by the degree of tissue contact and the convective cooling effects of blood flow.

Selecting Temperature When Using the Catheter (T°) in TEMPERATURE Control Mode

If a Catheter (T°) is connected to the Controller, a desired value of catheter tip temperature (temperature setpoint) can be selected. The Controller automatically adjusts power, within a user-selected upper power limit, to achieve the desired catheter tip temperature, in the Temperature Control mode.

To select the temperature setpoint for the Controller, follow these steps:

- 1.** Ensure that the Controller is in READY mode.

Operational Sequence 6-12

2. Press the appropriate TEMPERATURE (▲/▼) Button to increase or decrease the temperature setpoint by 1°C.

3. To scroll rapidly to the desired temperature setpoint, depress and hold the appropriate TEMPERATURE (▲/▼) Button down.

4. Release the TEMPERATURE (▲/▼) Button when the TEMPERATURE Display shows the appropriate temperature setpoint.

For high power catheters, the catheter tip temperature selection range is 30° to 80°C in increments of 1°C while for standard catheters, the catheter tip temperature selection range is 30° to 90°C in increments of 1°C, although the Controller cannot achieve a temperature which is less than the ambient blood temperature (normally 37°C).

5. During RF power delivery (RF Power ON mode), the temperature setpoint can be increased or decreased by pressing the appropriate TEMPERATURE (▲/▼) Button. When the TEMPERATURE (▲/▼) Button is depressed, the display shows the new temperature setpoint. When the button is released, the display shows the present value of catheter tip temperature. Depressing and holding the TEMPERATURE (▲/▼) Button down while RF power is being delivered does NOT cause the temperature setpoint to scroll up, but allows it to scroll down at a slightly greater rate than it does when the Controller is in the READY mode.

Selecting Temperature When Using the Catheter (T°) in POWER Control Mode

If a Catheter (T°) is connected to the Controller, an upper temperature limit can be selected. The Controller automatically decreases RF power to the Catheter if this value of temperature is exceeded in the Power Control mode.

To select the temperature setpoint for the Controller, follow these steps:

1. Ensure that the Controller is in READY mode.

2. Press the appropriate TEMPERATURE (▲/▼) Button to increase or decrease the upper temperature limit by 1°C during RF power delivery.

3. To scroll rapidly to the desired temperature setpoint, depress and hold the appropriate TEMPERATURE (▲/▼) Button down. (The temperature value shown in the TEMPERATURE Display is the maximum catheter tip temperature at which the Controller attempts to deliver RF power.)

4. Release the TEMPERATURE (▲/▼) Button when the TEMPERATURE Display shows the appropriate temperature setpoint.

The catheter tip temperature limit selection range is 55° to 85°C in increments of 1°C for high power catheters; 55° to 95°C in increments of 1°C for standard catheters.

6-13 Operational Sequence

Setting the Time Control

The TIME Display, TIME ▲ (increase) Button, and TIME ▼ (decrease) Button allow the user to select the duration (in seconds) that RF power is delivered to the Catheter.

To select the duration for RF power delivery, follow these steps:

1. Ensure that the Controller is in READY mode.

2. Press the appropriate TIME (▲/▼) Button to increase or decrease the RF power output duration (up to a maximum of 120 seconds).

3. To scroll rapidly to the desired duration, depress and hold the appropriate TIME (▲/▼) Button down.

4. Release the TIME (▲/▼) Button when the TIME Display shows the appropriate duration. (When the selected value is programmed into the Controller control circuit.)

Clearing the Counter

☐ **Important:** *Always clear the Counter between patients.*

1. To clear the counter to zero, depress the CLEAR Button.

2. Attempting to set the counter to greater than “99” will cause the counter to reset itself to zero.

Operational Sequence 6-14

Adjusting the Audio Control

The user may adjust the volume of the audio signal when the Controller is initially powered on or during a clinical procedure.

1. Adjust the volume of the audio signal by rotating the Volume Control Knob on the Controller rear panel (see Figure 6-10).

2. If desired during a clinical procedure, the Volume Control Knob may be rotated fully counter-clockwise to its lowest setting

⌘ **Note:** At the minimum setting, the tone may NOT be audible during RF power delivery.

Figure 6-10: Adjusting Audio Control

6-15 Operational Sequence

RF POWER
ANALOG OUTPUT SPEAKER
FOOT SWITCH RS-232
IMPEDANCE TEMPERATURE SPARE VOLUME

Volume Control Knob

To increase the volume of the audio signal, turn the Volume Control Knob clockwise.

To decrease the volume of the audio signal, turn the Volume Control Knob counter-clockwise.

VOLUME
VOLUME

Turning the RF Power Delivery “ON”

☐ **Important:** *Do not continue with this procedure unless all preceding procedures in this chapter have been completed.*

To deliver RF power to the Catheter, follow these steps:

1. Ensure that all connections are secure and correct.

2. Verify that all aforementioned selections have been made.

3. To begin RF power delivery, press the RF POWER CONTROL Button once or hold the Footswitch down. The POWER Display shows the RF power delivered to the Catheter (in W). The Audible tone sounds during RF power delivery.

⊗ **Note:** If the Controller is in the Temperature Control mode and the measured temperature is outside the range of 20°C to 43°C, the Controller does not deliver RF power and an E07 error code message displays.

When RF power is delivered to the Catheter, the displays function as follows:

RF POWER CONTROL BUTTON/Light

This light illuminates and remains lit until RF power delivery is discontinued. (For instructions on how to discontinue RF power delivery, see the section, *Turning the RF Power Delivery “OFF”* on page 6-20.

POWER Display

This display shows (in W) RF power delivered to the Catheter. The value may fluctuate slightly due to changes in tissue impedance.

Operational Sequence 6-16

TEMPERATURE Display

The readings on this display depend on the current control mode of the Controller (Power Control and Temperature Control), the operational mode, and the type of catheter connected. Table 6-1 summarizes the readings on the display under specified operating conditions.

6-17 Operational Sequence

Table 6-1: TEMPERATURE Display Readings

Catheter Type Control Mode TEMPERATURE Display Readings

Catheter (T°) Temperature • At initial power on, display reading is 30°C.

Control Mode • In READY mode, display shows the temperature setpoint.

- In ON, CALIBRATE, or DONE operational modes, display indicates measured catheter tip temperature.
- If the measured temperature is outside the range of 20°C to 43°C, the Controller does not deliver RF power.
- In ON operational mode:
 - If the temperature is within 20°C - 120° C orange, the measured temperature displays.
 - If the measured temperature is below 20°C, the message “LO” displays.
 - If the measured temperature is above 120°C, the message “HI” displays.

Catheter (T°) Power Control • In READY mode, display reading is 85°C for Mode high power catheters and 95°C for standard catheters.

- In ON, CALIBRATE, or DONE operational modes, display indicates measured catheter tip temperature.
- In ON operational mode:
 - If the temperature is within 20°C - 120° C range, the measured temperature displays.
 - If the measured temperature is below 20°C, the message “LO” displays.
 - If the measured temperature is above 120°C, the message “HI” displays.

Catheter (Non-T°) N/A • Display shows three dashes (---)

IMPEDANCE Display

This display shows measured impedance. The displayed readings may fluctuate slightly due to variation in the stability of electrode/tissue contact as the heart beats. If the measured value demonstrates a significant fluctuation, the Catheter should be repositioned.

Alternatively, slight pressure on the Catheter shaft may minimize Catheter motion. Table 6-2 summarizes the readings on the display by impedance range.

Operational Sequence 6-18

Table 6-2: Impedance Display Readings

Impedance Operating Condition Controller Activity Display

Values Reading

Typical Impedance Normal operating Normal RF power Display shows condition delivery measured 80 to 150 Ω impedance

Low Impedance:

< 50 Ω If accessing up to 50 W Controller automatically Display flashes of RF power shuts off RF power “LO”

< 25 Ω If accessing up to 100 W Controller automatically Display flashes of RF power shuts off RF power “LO”

High Impedance: For both 50W or 100W Controller automatically Display flashes power limits shuts off RF power between

> 300 Ω measured impedance and “HI”

1. Low impedance limit depends on type of catheter used in the ablation procedure.
2. High Impedance indicates abnormal operation. This condition also may occur if > 1 A is detected by the XP APM from either DIPElectrode. Refer to the following procedure, *Correcting a High Impedance Condition*.

Correcting a High Impedance Condition

If a high impedance value is detected during RF power delivery, follow these steps:

1. Ensure that the connection between the Catheter and APM (either APM or XPAPM) is correct and secure.
2. Ensure that the connection between each DIP Electrode and APM (either APM or XPAPM) is correct and secure.
3. Ensure that each DIP Electrode is properly applied.
4. If an improper cable connection is not the cause of the high impedance value, then a build-up of coagulum on the Catheter tip may be the cause, and RF power output should be discontinued.
5. To discontinue RF power delivery, refer to the instructions in section, *Turning the RF Power Delivery “OFF”* on page 6-20.

TIME Display

This display shows the user-selected value and elapsed time as follows:

- When the RF POWER CONTROL Button is pressed or the Footswitch is depressed, this display changes from the user-selected time limit to 0 seconds and begins to count up to the user-selected value.
- When the preset duration has elapsed, the RF power automatically shuts “OFF.” The user-selected value remains flashing on the TIME Display.
- If the RF POWER CONTROL Button is pressed during delivery of RF power or the Footswitch is released, the RF power output immediately turns “OFF.” The actual elapsed time in seconds remains flashing on the TIME Display.

COUNTER Display

This display increases by 1 count with each RF power delivery. The value resets to zero at any time when the Controller is in the READY mode. Attempting to set the counter to “99” also will reset the counter to zero.

CONTROL Display

This display indicates the Controller’s current control mode (Power Control or Temperature Control). The green LEDs indicate when the Controller is either in the Power Control or Temperature Control modes, respectively.

6-19 Operational Sequence

Directions for Use

Refer to the Blazer II XP™ Cardiac Ablation Catheter Directions For Use for catheter directions for use.

Turning the RF Power Delivery “OFF”

To discontinue RF power delivery during operation (RF Power Done mode), the user may either:

- Press the RF POWER CONTROL Button or
- Release the Footswitch.

☒ **Note** RF power delivery ceases by user intervention or certain operating conditions listed in the next section, Possible Causes of RF Power Delivery Interruption.

Possible Causes of RF Power Delivery Interruption

RF power delivery can cease due to other operating conditions other than user intervention.

RF power ceases when:

- User-selected time limit has been reached.
- XP APM detects greater than 1 A in either of the two DIP Electrodes.
- Impedance is less than 50 Ω when accessing up to 50 W of RF power.
- Impedance is less than 25 Ω when accessing up to 100 W of RF power.
- Impedance is greater than 300 Ω .
- Temperature exceeds setpoint by 5°C for greater than four seconds (Controller in Temperature Control mode).
- Temperature exceeds 85°C for high power catheters or 95°C for standard catheters for greater than one second (Controller in Power Control or Temperature Control mode with a Catheter (T°) connected).
- Temperature is less than 20°C for greater than one second.
- Temperature exceeds temperature setpoint in Power Control mode (e.g., If temperature is set at 60°C and measured temperature exceeds 60°C, RF power shuts off).
- Upper temperature limit is exceeded twice during a single RF power delivery in Power Control mode.
- System operation errors are detected.

Operational Sequence 6-20

Display Readings During Interruption of RF Power Delivery

When RF power delivery ceases for any reason other than an out-of-range impedance value or an error, the last value appearing on each display remains flashing and the RF POWER CONTROL Light turns “OFF.”

If RF power delivery ceases due to an out-of-range impedance value, the last measured impedance value remains flashing on the IMPEDANCE Display, alternating with the appropriate “HI” or “LO” message.

If RF power delivery ceases due to an error, the last measured impedance value remains flashing on the IMPEDANCE Display, alternating with the appropriate error code. (See Table 8-3 for a listing of error codes.)

In any of the above cases, when either the RF POWER CONTROL Button or the Footswitch is depressed again, the flashing display values change immediately to the previous user-selected values and the RF POWER CONTROL Light begins flashing. This signals that the Controller is ready for additional RF power deliveries. This is true unless RF power delivery, while in the Power Control mode, is interrupted for exceeding the upper temperature limit a second time. In this case, the set power is 50% of the value of RF power which causes the upper temperature limit to be exceeded.

6-21 Operational Sequence

7. Service and Maintenance

The Controller requires no routine service or maintenance. If the Controller fails to operate when plugged into a proper AC power receptacle and the power switch is turned on, check the fuse (refer to *Replacing the Fuses* in this chapter).

The Controller contains no user-serviceable parts; disassembly and attempted repair by unqualified personnel may create a hazardous condition and voids the warranty.

☎ Call BSC for Service: If a second failure occurs, notify BSC for service (Customer Service Telephone Number: 1-800-552-6700)

■ **Precaution:** Do not remove the cover of the Controller. Removing the cover may result in personal injury and/or damage to the Controller.

Cleaning/Disinfecting

The outer surfaces of the Controller and its accessories may be cleaned with a mild soapy solution. If disinfecting is required, isopropyl alcohol may be used to clean the outer surfaces.

■ **Precaution:** Do not immerse the Controller or its accessories in any liquid. Avoid caustic or abrasive cleaners.

Replacing the Fuses

Replacing the MAINS Fuse

1. Before replacing a fuse in the Controller, disconnect the MAINS power cord from the Controller.
2. Replace the fuse with another of the same type and rating. Refer to the fuse label on the rear panel (see Figure 5-10).
3. Pull the fuse holder out of the power entry module.
4. Use a screwdriver to assist in removing the fuse holder.
5. Insert the new fuse in the fuse holder and reinsert it in the power input module.

☒ **Note:** When replacing the fuse holder, ensure the fuse holder is inserted in the correct orientation for the operational voltage level.

Service and Maintenance 7-1

Auxiliary Power Outlet Fuses

1. Before replacing a fuse in the Controller, disconnect the MAINS power cord from the Controller.
2. Replace the fuse with another of the same type and rating. Refer to the fuse label on the rear panel (see Figure 5-10).
3. Use a screwdriver to rotate the fuse holder counter-clockwise 1/8th of a turn. The fuse holder “pops” out approximately 6 mm (1/4-inch).
4. Remove the fuse holder and the fuse.
5. Insert the new fuse in the fuse holder and reinsert it into the housing.

☎ **Call BSC for Service** If there appears to be a problem with the Controller, please contact BSC for instructions on returning the Controller to Boston Scientific Corporation for repair (Customer Service Telephone Number: 1-800-552-6700)

7-2 Service and Maintenance

8. Product Specifications

General Specifications

Table 8-1 lists the specifications for the System (Controller and XPAPM).

Product Specifications 8-1

Table 8-1: System Specifications

Description Specification

Power Specifications

Line Power 100 - 120 VAC (Model #800XP)

Current Rating

Fuse Rating 3 A, 50/60 Hz (100 - 120 VAC)

Auxiliary Power 100 - 120 VAC (Model #800XP)

Current Rating

Fuse Rating 1 A, 50/60 Hz (100 - 120 VAC)

Power Length Cord 10 ft

Footswitch

Cable Length 10 ft, Connector (to Controller): Polarized

Patient Cable to Extended

Performance Automatic

Personality Module

Length 10 ft

Connector "Multi-pin" Polarized Connector

High Power Automatic Personality Module

Dimensions

Height 1.8" (4.6 cm)

Width 5.9" (15.0 cm)

Depth 3.1" (7.9 cm)

Weight 2.2 lb (1.0 kg)

8-2 Product Specifications

Table 8-1: System Specifications, Continued

Description Specification

High Power Automatic Personality Module, Continued

Recorder Connectors Quick Connect Connector

Catheter Connectors Quick Connect Connector

Indifferent Electrode Connectors Standard male 2-pin for commercial pads

Recorder Filters

Low Pass Filters Referenced to the INDIFFERENT

ELECTRODE

Low Frequency Cutoff 5 kHz, -3dB at 5 kHz \pm 2 kHz

High Power Disconnect Mechanism RF output ceases to the patient if more than 1 A flows in either INDIFFERENT

ELECTRODE

Automatic Personality Module

Dimensions

Height 1.5" (3.8 cm)

Width 4.5" (11.4 cm)

Depth 1.8" (4.6 cm)

Weight 16 oz (453.6 g)

Recorder Connectors Quick Connect Connector

Catheter Connectors Quick Connect Connector

Indifferent Electrode Connectors Standard male 2-pin for commercial pads

Controller

RF Power Outputs • 50 W maximum into a minimum impedance of 50 Ω , within a 1 A current limit

• 100 W maximum into a minimum impedance of 25 Ω , within a 2 A current limit

Maximum RF power output based on catheter type used and control mode.

Product Specifications 8-3

Table 8-1: System Specifications, Continued

Description Specification

Controller, Continued

Impedance • Measures 50 Ω and above, if accessing up to 50 W of RF power

• Measures 25 Ω and above, if accessing up to 100 W of RF power

• Measures up to 999 Ω (Controller automatically shuts off RF power at 300 Ω)

- Displays “LO” or “HI” outside the 25 Ω to 300 Ω range

Temperature

With Catheter (T°) Connected and Allows selection of desired catheter tip

Controller in Temperature Control temperature (temperature setpoint) within

Mode the range of 30° to 80°C for high power catheters and 30° to 90°C for standard catheters

With Catheter (T°) Connected and Allows selection of upper temperature

Controller in Power Control Mode limit or maximum temperature at which the Controller continues to deliver the setpower

Normal Operating Condition: Controller measures 20° to 120°C

With Controller in the Temperature

Control or Power Control Modes

Outside of Normal Operating Range Controller displays “LO” or “HI”

Dimensions

Height 8” (20 cm)

Width 13” (33 cm)

Depth 21” (53 cm)

Weight 23 lb (10.4 kg)

Time 0 to 120 seconds in increments of
1 second

Counter 0 to 99 RF power deliveries

8-4 Product Specifications

Table 8-1: System Specifications, Continued

Description Specification

Controller, Continued

Low-Frequency Leakage (50/60 Hz);

Source Current, Patient Leads, All Outputs

Tied Together

Normal Polarity, Intact Chassis <10 μ A

Ground

Normal Polarity, Ground Open <10 μ A

Reverse Polarity, Ground Open <10 μ A

Sink Current, at 120 V Applied, All <10 μ A

Inputs

Chassis Source Current, Ground Open <100 μ A

Calibration Mode

Power Output 0 - 1 volt corresponds to 0 - 100 W, continuous square wave

Impedance 0 - 1 volt corresponds to 0 - 300 Ω , continuous square wave

Temperature 0 - 1 volt corresponds to 20 - 120°C, continuous square wave

Environmental Specifications

Table 8-2 lists the environmental specifications for the System.

Product Specifications 8-5

Table 8-2: Environmental Specifications

Description Specification

Storage

Temperature -40°C to 70°C

The unit should be gradually returned to the operating temperature range before use and stabilized for one hour before operation.

Relative Humidity 10% to 100%, non-condensing

Atmospheric Pressure 500 to 1060 millibar

Operating

Temperature 10°C to 40°C

Relative Humidity 30% to 75%, non-condensing
Atmospheric Pressure 700 to 1060 millibar

Power Delivery

As an enhanced patient safety feature, the output voltage and current of the System has been limited. Under normal circumstances (normal patient impedances), the maximum output power of the System is either 50 or 100 W, depending on catheter type and control mode. In the event of unusually high or low tissue impedance, the System limits the maximum power. A graph which depicts the maximum output power of the System as a function of tissue impedance is shown in Figure 8-1.

⚠ **Note:** Only the maximum power is affected. If the power setting is less than the maximum power available, the System delivers the set power value.

Figure 8-1: Output Power vs. Tissue Impedance

8-6 Product Specifications

20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320 340 360

100W, 2A

SW v2.01 (50 Watt)

P

(Watts)

Z

(Ohms)

10

100

90

80

70

60

50

40

30

20

Error Codes

Table 8-3 defines the error codes for the EP Technologies Cardiac Ablation System.

E01-E03 Error Codes

If error codes E01-E03 are observed, it is recommended that the ablation be attempted again.

☎ **Call BSC for Service** If the error code displays again, notify BSC for service. See Section 7, *Service and Maintenance* in the Operator's Manual.

E06 Error Code

If an E06 error code message occurs, turn the Controller "OFF." Wait approximately five seconds before turning the Controller "ON."

☎ **Call BSC for Service** If the Controller does not successfully pass the self-test procedure, or if the E06 error code message occurs again following successful completion of the self-test procedure, notify BSC for service. See Section 7,

Service and Maintenance in the Operator's Manual.

Product Specifications 8-7

Table 8-3: Error Codes

Code Description

E01 Apparent power ($V_{rms} * I_{rms}$) not greater or equal to real power

E02 Apparent power ($V_{rms} * I_{rms}$) measured greater than the setpoint

E03 Limit exceeded: $V > V_{max}$ or $I > I_{max}$ or $P > P_{max}$

E04 Temperature is greater than setpoint by at least 5°C for greater than four seconds

E05 Temperature greater than 85°C for high power catheters, greater than

95°C for standard catheters, or less than 20°C for greater than

1 second

E06 System Operation Error

E07 An attempt to enter RF Power On mode with a measured temperature outside the range of 20°C to 43°C.

E08 Upper temperature limit (cutoff) exceeded for more than 4.0 seconds.

E09 Upper temperature limit (cutoff) exceeded for the second time.

Figure 8-2: Labeling Symbols

8-8 Product Specifications

Power ON Power OFF Temperature at

Distal Electrode

Degree C

Alternating

Current

Increase Decrease Protective

Earth Ground

Defibrillator-Proof

Type Equipment

Variability Clock:

Time Switch:

Timer

Dangerous

Voltage

Attention, Consult

Accompanying

Documents

Non-Ionizing

Radiation

Loudspeaker Fuse Counter

Calibration Clear Indifferent

(Dispersive)

Patch Electrode

Radio Frequency

Power (On/Off)

Equipotentiality

000

M

Explosion

Hazard

AP

9. Limited Warranty and Disclaimer

Warranty and Limitations

Boston Scientific warrants that this product is free from defects in original workmanship and materials. If this product is proved to be defective in original workmanship or original materials, Boston Scientific, in its absolute and sole discretion, will replace or repair it, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products which have been used for their normal and intended uses. Boston Scientific's limited warranty shall NOT apply to Boston Scientific products which were installed or calibrated by persons not authorized by Boston Scientific or which have been repaired, altered, or modified in any way and shall NOT apply to Boston Scientific products which have been improperly stored or improperly installed, operated or maintained contrary to Boston Scientific's instructions.

U.S. 5195968; U.S. 5254088; U.S. 5257451; U.S. 5336182; U.S. 5363861; U.S. 5364351; U.S. 5363874; U.S. 5273535; U.S. 5358478; U.S. 5395327; U.S. 5456682; U.S. 4566682; U.S. 5531686; U.S. 5524337; U.S. 5309910; U.S. 5313943; U.S. 5398683; U.S. 5471982; U.S. 5549108; U.S. 5489275; U.S. 5328467; other U.S. patents pending; foreign counterparts also pending.

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